

**Fax**

*Lilly*

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**Date: 25 May 2004**

**To:** Examiner R. DeBerry  
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**Total Pages:** 34

**Privileged and Confidential Communication**

**Subject:** Re: U.S. Patent Application No. 09/928,198  
Our Reference: X-12383N

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**Answers That Matter.**

**CERTIFICATION OF FACSIMILE TRANSMISSION**

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JANET M. FOWLER

Type or print name of person signing certification

Signature

Janet M. Fowler

5/25/04

Date

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants	:	James A. Hoffmann and Jirong Lu	)	
			)	
Serial No.	:	09/928,198	)	
			)	Group Art Unit:
Filed	:	August 10, 2001	)	1647
			)	
For	:	FSH FORMULATION	)	Examiner:
			)	R. DeBerry
Docket No.	:	X12383N	)	

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Under the guidelines of 37 C.F.R. 1.97, Applicants submit a copy of each of the documents listed on the attached Form PTO-1449 (modified) for consideration by the Examiner.

Since this Statement is being filed after the period specified in §1.97(c), but before the mailing date of a notice of allowance, attached is a certification under §1.97(e). Please charge the amount of \$180.00, the fee under 37 C.F.R. 1.17(p), and charge any additional fees which may be required by this or any other related paper, or credit any overpayment to Deposit Account No. 05-0840.

Serial No. 09/928,198

-2-

Applicants respectfully request consideration of this information.

Respectfully submitted,

*Paula K. Davis*

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May 25, 2004

## CERTIFICATION OF FACSIMILE TRANSMISSION

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Janet M. Fowler

5/25/04

Date

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants	:	James A. Hoffmann and Jirong Lu	)	
Serial No.	:	09/928,198	)	
International Filing Date	:	August 10, 2001	)	Group Art Unit: 1647
For	:	FSH FORMULATION	)	Examiner: R. DeBerry
Docket No.	:	X12383N	)	

**CERTIFICATION UNDER 37 C.F.R. §1.97 (e)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Under the guidelines of 37 C.F.R. §1.97(e), I hereby certify that:  
no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this statement.

Respectfully submitted,  
Paula K. Davis  
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Patent Division/PKD  
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May 25, 2004

Sheet 1 of 1

FORM PTO 1449 (modified)  INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Atty. Docket No. X12383N	Serial No 09/928,198
	Applicants James A. Hoffmann and Jirong Lu	
	Filing Date August 10, 2001	Group 1647

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T <sup>6</sup>
	CCB	SERONO Study Report GF 9873, "Evaluation of FSH Formulations claimed in EP-974'359," dated March 22, 2004	
	CCC	European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products (CPMP), "Note for Guidance on Maximum Shelf-life for Sterile Products for Human Use After First Opening or Following Reconstitution," Guidance CPMP/QWP/159/96, 1999.	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the kind of two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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